

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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CHRISTEL BILLHOFER, On Behalf of  
Herself and All Others Similarly Situated,

Plaintiff,

vs.

FLAMEL TECHNOLOGIES, SA, STEPHEN  
H. WILLARD, and RAFAEL JORDA,

Defendants.  
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Civ. No. 07 Civ. 9920 (CSH)

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(ECF Case)

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**REPLY MEMORANDUM OF LAW BY FLAMEL TECHNOLOGIES, SA  
IN SUPPORT OF ITS MOTION TO DISMISS THE AMENDED COMPLAINT**

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Dated: August 19, 2008

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Defendant Flamel Technologies, SA ("Flamel") respectfully submits this reply memorandum of law in further support of its motion to dismiss, with prejudice, the claims asserted against it in the Amended Complaint (the "Amended Complaint" or "AC").

### **PRELIMINARY STATEMENT**

In its moving brief, Flamel demonstrated that plaintiff's two claims under §§10(b) and 20(a) of the Securities Exchange Act of 1934 should be dismissed because (a) the facts pled showed that the only statement plaintiff allegedly relied upon before buying her Flamel securities -- a March 23, 2007 Flamel press release -- was not materially misleading and (b) no facts had been pled sufficient to raise a strong inference of scienter. Hamstrung both by what she pled and what she omitted, plaintiff has attempted to defend her claims by distorting the facts alleged and speculating about those that were not. Plaintiff's arguments should be rejected.

Plaintiff contends that the March 23 press release was materially misleading because it described the release of COREG CR, a drug Flamel developed with GlaxoSmithKline, as a "success" but omitted to disclose the results of the clinical CASPER trial (later published in August 2007), which supposedly showed that patient compliance rates -- the rate patients comply with their drug prescriptions -- for COREG CR had not improved over the existing COREG IR drug.

That argument fails because (a) read in context, the March 23 press release shows that "success" referred to the technical attributes of Flamel's "micropump" technology -- which had indisputably proven successful -- and not to patient compliance rates; and (b) the facts pled show that the "market" was not misled by the March 23 press release about the CASPER trial results. Further, plaintiff simply ignores established caselaw holding that vague expressions of corporate optimism -- such as Flamel's use of the word "success" -- are immaterial as a matter of law and cannot support a securities action.

As for her scienter-related allegations, plaintiff's claim that she properly pled motive is meritless because (a) she fails to identify any concrete benefit Flamel officers obtained as a result of the alleged fraud; (b) the asserted "motive" amounts to a desire to maintain the appearance of corporate profitability, which has consistently been held insufficient; and (c) the scheme alleged was doomed to fail from the start and thus is so economically irrational that it cannot support a §10(b) claim.

Plaintiff's defense of her "conscious recklessness" pleading is similarly flawed. Plaintiff's argument rests on the assertion that, because Flamel supposedly "ran" the CASPER trial, it "must have known" the trial results. No facts, however, are pled to support plaintiff's belief that Flamel "ran" the trial. Worse still, Flamel's status as a trial "sponsor" does not support an inference that it learned the trial results before they were published in August 2007 -- and no facts are pled to show that the trial results were conveyed to anyone at Flamel prior to publication. Plaintiff's claim that Flamel "must have known" the trial results is simply an attempt to plead fraud by hindsight and should be rejected.

### **ARGUMENT**

#### **I. PLAINTIFF'S §§10(B) AND 20(A) CLAIMS SHOULD BE DISMISSED**

##### **A. Plaintiff Fails To Allege A Material Misstatement**

As Flamel showed in its moving brief, plaintiff's §10(b) claim must fail because Flamel's March 23, 2007 press release was not materially misleading. (Def. Br. at 7-9.) Plaintiff argues otherwise, contending that the press release's characterization of COREG CR as a "success" rendered the disclosure materially misleading because it omitted that the CASPER trial had supposedly shown that patient compliance rates for COREG CR had not improved over COREG IR. (Pltf. Br. at 6-10.) Plaintiff's argument is wrong.

**1. The March 23, 2007 press release was not misleading**

Plaintiff's argument rests on the proposition that, because the "market" allegedly viewed COREG CR's "success" as intertwined with patient compliance rates, Flamel's use of the word "success" in its March 23 press release imposed upon it the duty to disclose the CASPER trial results. (Pltf. Br. at 7-8.) That position is untenable.

Contrary to plaintiff's contention, a "corporation is not required to disclose a fact merely because a reasonable investor would very much like to know that fact" nor must a corporation, when it "speaks ... disclose every piece of information in its possession that could affect the price of its stock." *In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 267-268 (2d Cir. 1993). Rather, a "duty to disclose arises" only when "secret information renders prior public statements materially misleading." *Id.* at 268. Accordingly, to plead a misstatement, plaintiff must demonstrate that "the alleged omissions ... are sufficiently connected to Defendants' existing disclosures to make those public statements misleading." *In re Marsh & McLennan Cos., Inc. Sec. Litig.*, 501 F. Supp. 2d 452, 469 (S.D.N.Y. 2006).

That essential connection is missing in this case. When Flamel's use of the term "success" is reasonably construed in the context of the March 23 press release, as the Second Circuit has instructed,<sup>1</sup> it cannot be understood as referring either to patient compliance rates for COREG CR or to the product's market potential -- and thus did not trigger a duty to disclose the CASPER trial results (even if those results had been known by Flamel).

Rather, the text of the press release shows that its use of the term "success" could reasonably be understood as referring only to the technical attributes of Flamel's "micropump"

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<sup>1</sup> See *Rombach v. Chang*, 355 F.3d 164, 172 n.7 (2d Cir. 2004) ("a statement is materially misleading ... [if] 'defendants' representations, taken together and in context, would have misled a reasonable investor'").

technology, which enabled the "controlled release" essential to the development of COREG CR.<sup>2</sup> Further, there is no dispute that those technical attributes were a success. For example, plaintiff does not challenge that Flamel's "micropump" technology permitted the controlled release of the medical agent in COREG CR. Nor does plaintiff dispute that the FDA approved the sale of COREG CR, thereby acknowledging that Flamel's technology was both safe and effective. Accordingly, in every reasonable way in which Flamel's use of the word "success" could be interpreted, its statement in the press release was entirely accurate.<sup>3</sup>

Moreover, it is readily apparent that plaintiff's contention of how the "market" understood the March 23 press release -- *i.e.*, as announcing "success" with respect to improved patient compliance rates -- is nothing but implausible speculation, which cannot support a claim. *See ATSI Communications, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007)(complaint must contain "factual allegations sufficient 'to raise a right to relief above the speculative level'"). For example, the Amended Complaint fails to site a single securities analyst who understood Flamel's use of "success" to mean that the CASPER trial had found improved patient compliance rates for COREG CR.

Nor is such silence surprising. Given the market's supposed focus on patient compliance rates as the benchmark for COREG CR's future market potential, it would have been

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<sup>2</sup> As quoted in the Amended Complaint (AC ¶ 22), the March 23 press release, in relevant part, said:

COREG CR™ is the first marketed product incorporating Flamel's MICROPUMP® technology. The success of the COREG CR™ program has generated considerable interest in our MICROPUMP® technology as well as in our MEDUSA® technology platform for the delivery of proteins and peptides. Interest in both technologies has never been higher.

<sup>3</sup> Plaintiff argues that the press release's statement that the "success" of COREG CR "has generated considerable interest" was misleading because that interest was "a result of the false belief that COREG CR was a 'success.'" (Pltf. Br. at 7.) That argument is not only circular, but unfounded because plaintiff fails to identify any Flamel statement prior to March 23 in which it "falsely" described COREG CR as a "success." Accordingly, the "considerable interest" described in the March 23 press release could not have been the product of misinformation about COREG CR.



anomalous for Flamel to have announced COREG CR's satisfaction of that critical hurdle using the language employed by the March 23 release -- or for the "market" to have understood the release in that manner. Moreover, plaintiff concedes that, after March 23, the "market" did not believe that COREG CR had obtained "success" in the supposedly critical area of patient compliance rates. Specifically, as pled in the Amended Complaint, securities analysts, through May and August 2007, continued to ask when the CASPER trial results would be published and what they would show. (AC ¶¶ 25, 27.)

In sum, the facts pled demonstrate that the March 23 press release did not misuse the term "success" nor did the "market" misunderstand the press release as plaintiff posits. Plaintiff's claim must therefore fail.

## **2. The term "success" was not material**

Even if some investors might have misconstrued the March 23 press release's use of the term "success" as referring to patient compliance rates, the term itself was not material and thus cannot support a §10(b) claim. As previously shown (Def. Br. at 9), courts have consistently held vague expressions of corporate optimism which are "not capable of objective verification" to be immaterial as a matter of law. *See In re Tower Automotive Sec. Litig.*, 483 F. Supp. 2d 327, 336 (S.D.N.Y. 2007). The March 23 press release's use of the term "success" -- without further amplification or objective quantification -- is a quintessential example of such immaterial corporate puffery. Indeed, numerous courts have held that "nebulous and unmeasurable claims of 'success' ... are just the sort of statements not properly the subject of a securities fraud claim." *Id.* at 337.<sup>4</sup>

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<sup>4</sup> *Accord Grossman v. Novell, Inc.*, 120 F.3d 1112, 1121-22 (10<sup>th</sup> Cir. 1997)(disclosure that issuer had "'substantial success' in integrating" acquired sales force is non-actionable puffery); *In re Razorfish, Inc. Sec. Litig.*, No. 00 Civ. 9474 (JSR), 2001 WL 1111502, at \*2-3 (S.D.N.Y. Sept. 21, 2001)(same); *Kane v. Madge Networks N.V.*, No. C-96-20652-RMW, 2000 WL 33208116, at \*3-4 (N.D. Cal. May 26, 2000)(description of marketing relationship as "successful" is puffery); *aff'd*, 32 Fed. Appx. 905 (9<sup>th</sup> Cir. 2002); *In re Peritus Software Services, Inc. Sec. Litig.*, 52 F. Supp. 2d 211, 229 (D. Mass. 1999)(calling merger a "success" is not actionable).

Plaintiff ignores the established law on corporate puffery and instead contends -- citing *In re Regeneron Pharmaceuticals, Inc. Sec. Litig.*, No. 03 Civ. 3111 (RWS), 2005 WL 225288 (S.D.N.Y. Feb. 1, 2005) -- that characterizing a drug, which is critical to a company's business, a "success" is always material.<sup>5</sup> (Pltf. Br. at 9.) The *Regeneron* decision, however, did not adopt such a sweeping rule and the facts of that case readily distinguish it from this action. Specifically, the *Regeneron* Court found the defendant's misstatements material because they constituted detailed and quantifiable pronouncements about the safety and efficacy of its proposed drug.<sup>6</sup> *Id.* at \*8, 21 ("[s]tatements regarding the overall efficacy of the drug ... cannot be simply dismissed as immaterial"). Those detailed disclosures stand in marked contrast to Flamel's bald use of the word "success" and illustrate why Flamel's vague word choice -- which, as shown by plaintiff's own tortured arguments, is inherently imprecise -- is immaterial as a matter of law. Accordingly, plaintiff's claim must fail.

## **B. Plaintiff Fails To Allege Facts Raising A Strong Inference Of Scienter**

Flamel's moving brief showed that plaintiff's §10(b) claim should be dismissed for the independent reason that the Amended Complaint fails to allege facts raising a strong inference of scienter. (Def. Br. at 11-17.) Plaintiff's arguments do not warrant a different conclusion.

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<sup>5</sup> Plaintiff also argues that the term "success" was material because Flamel's stock price supposedly fell when the allegedly omitted information -- *i.e.*, the CASPER trial results -- was disclosed. (Pltf. Br. at 8 n.5.) Plaintiff's focus on the omitted information, however, is misguided because an immaterial statement cannot alter the "total mix of information" and thus does not trigger a disclosure duty. *See In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999)(statements amounting to corporate puffery "even if arguably misleading, do not give rise to a federal securities claim because they are not material").

<sup>6</sup> For example, the defendant misrepresented that its drug "showed medically meaningful and statistically significant weight loss;" was "well tolerated and was not associated with any serious adverse events;" and that "[n]eutralizing antibodies" which would undermine the drug's efficacy "were not dose-related and occurred in less than 10% of all patients receiving" the drug. *Regeneron*, 2005 WL 225288, at \*8.

# **1. Plaintiff fails to allege any motive to commit fraud**

As shown, plaintiff has not only failed to allege a viable motive for Flamel to commit fraud, but the scheme pled is economically irrational because it posits that Flamel issued allegedly misleading disclosures beginning on March 23, 2007, supposedly knowing that the "truth" would be publicly disclosed by August 2007. (*Id.* at 11-13.) Plaintiff's three rebuttal arguments are each flawed.

First, plaintiff contends that she has pled a viable motive -- *i.e.*, Flamel's desire to make the release of COREG CR, the first product incorporating Flamel's technology, appear commercially successful. (Pltf. Br. at 11-12.) A properly pled motive, however, "must be one that will accrue to the individual defendants; general benefits to the corporation will not suffice." *In re IPO Sec. Litig.*, 358 F. Supp. 2d 189, 214 (S.D.N.Y. 2004). In this case, the Amended Complaint does not assert that Flamel's officers sold stock or received any other benefit as a result of the alleged fraud.

Further, plaintiff's articulated motive is applicable to any company launching its first product and thus it violates the basic rule that a properly pled motive "may not be based on the types of motives shared by virtually all public companies and corporate insiders." *Albert Fadem Trust v. Citigroup, Inc.*, 165 Fed. Appx. 928, 930 (2d Cir. 2006). Indeed, the Second Circuit has consistently rejected plaintiff's theory, holding that "'the desire to ... sustain the appearance of corporate profitability, or of the success of an investment'" is insufficient to allege a securities fraud. *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 196-97 (2d Cir. 2008).

Second, plaintiff argues that the alleged scheme was not irrational because publication of the CASPER trial results in August 2007 was not assured. (Pltf. Br. at 13 n.7.) Plaintiff, however, ignores the implications of her own pleadings -- *i.e.*, that the CASPER trial researchers had determined to publish their findings. Whether their article appeared in the August 2007 *Journal of Cardiac Failure* (as allegedly happened) or in some other periodical, the CASPER trial results inevitably would be

published. Accordingly, because the alleged scheme was doomed to fail from the start -- because the "truth" would inevitably be disclosed -- plaintiff's theory is nonsensical.

Third, plaintiff argues that even a short-lived scheme would be rational because it would permit Flamel to enter new partnership agreements with other drug companies. (Pltf. Br. at 12, 13 n.7.) Plaintiff's idle speculation finds no factual support in the Amended Complaint; defies common sense;<sup>7</sup> and simply recycles the inadequate claim that Flamel desired to maintain the appearance of corporate profitability. Accordingly, it can not raise any inference -- let alone a strong one -- of scienter.

## **2. Plaintiff fails to allege facts showing conscious recklessness**

Plaintiff's contention that she has pled facts raising a strong inference of conscious recklessness rests on the claim that Flamel "ran" the CASPER trial and "must have known" the trial results because of the importance of patient compliance rates to the commercial success of COREG CR. (Pltf. Br. 14-16.) Neither of these conclusory assertions, however, suffice to satisfy the PSLRA's heightened factual pleading standard.

First, contrary to plaintiff's argument (Pltf. Br. at 14), her allegation that Flamel "ran" -- or, as the Amended Complaint (AC ¶ 18) contends "commenced" -- the CASPER trial is not a factual averment but simply a conclusory assertion which, given plaintiff's lack of personal knowledge, must be accompanied by facts supporting her belief to satisfy the PSLRA's particularity requirements. 15 U.S.C. §78u-4(b)(1); *Novak v. Kasaks*, 216 F.3d 300, 313-14 (2d Cir. 2000) (plaintiff must "plead with particularity *sufficient* facts to support" alleged belief). No such facts are pled. Moreover, because the documents plaintiff relied upon in drafting the Amended Complaint contradict her conclusory allegation -- because they point to GlaxoSmithKline as the sponsor of the CASPER trial, not Flamel

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<sup>7</sup> For example, plaintiff's argument assumes, without any factual support, that Flamel could identify and execute a new partnership agreement within the five-month period of the alleged scheme and that drug companies would be persuaded to partner with Flamel based upon the allegedly misleading press releases.

(Def. Br. at 16-17 & nn. 21-22) -- her contention "need not be accepted" as true. *Tower Automotive*, 483 F. Supp. 2d at 334.

Second, even assuming that Flamel "ran" the CASPER trial, that alone would not suffice to raise a strong inference of scienter. As the Second Circuit has held, "'a pleading technique [that] couple[s] a factual statement with a conclusory allegation of fraudulent intent' is insufficient" to satisfy the PSLRA. *Rombach*, 355 F.3d at 176.

Flamel's purported status as "sponsor" of the CASPER trial fails to raise an inference that Flamel knew the results of the trial at any time prior to their publication in August 2007. Courts have consistently rejected a defendant's "status" as a sufficient basis to infer scienter.<sup>8</sup> That is because such an inference hinges on the assumption that the defendant either (a) could have (but failed) to discover the "truth" or (b) did learn the "truth." The former suggests only negligence, which cannot support a §10(b) claim. *Chill*, 101 F.3d at 270 ("[f]raud cannot be inferred simply because [defendant] might have been more curious or concerned"). The latter assumption does not satisfy the PSLRA's heightened pleading standard. Rather, plaintiff must have "specifically alleged defendants' knowledge of facts or access to information contradicting their public statements" and "specifically identify the reports or statements containing this information." *Novak*, 216 F.3d at 308-09; Def. Br. at 15 & n.19.

Those facts are wholly absent from the Amended Complaint. Neither in her pleadings nor her brief does plaintiff identify any facts -- whether through a witness or a document -- showing that the CASPER trial results were conveyed to anyone at Flamel prior to their publication on August 23, 2007. In the absence of such facts, plaintiff's assertion that the results were so important to COREG

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<sup>8</sup> See, e.g., *Chill v. General Electric Co.*, 101 F.3d 263, 270-71 (2d Cir. 1996)(parent company not assumed to know subsidiary's accounting information); *Goplen v. 51job, Inc.*, 453 F. Supp.2d 759, 773 (S.D.N.Y. 2006)(Haight, J.)(defendants' executive position insufficient to infer knowledge of information contained in corporate files).

CR's commercial success that Flamel "must have known" them is nothing but an improper attempt to plead fraud by hindsight, which must be rejected. *See Bay Harbour Management LLC v. Carothers*, No. 07-1124-CV, 2008 WL 2566557, at \*2 (2d Cir. June 24, 2008)(claim that defendants "must have known" at time of bond offering of later published valuations improperly pleads fraud by hindsight).

Moreover, in the absence of any facts suggesting scienter, the inferences of non-fraudulent intent are far more compelling. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S.Ct. 2499, 2504-05 (2007). For example, because plaintiff alleges (AC ¶ 19) that April 9, 2007 was the submission date for the CASPER trial article, it is reasonable to infer that the trial results were not known to the researchers (let alone Flamel) when Flamel issued its March 23 press release. Equally reasonable is the inference that, to preserve their scientific independence, the CASPER trial researchers did not leak their findings to Flamel. Further, as discussed (Def. Br. at 17), the facts alleged weigh against a finding of scienter because (a) statements by Flamel's CEO are consistent with Flamel not knowing of the CASPER trial results and (b) through at least August 1, 2007, Flamel was manufacturing COREG CR microparticles at the "maximum" rate, which it would not have done had it known that the CASPER trial results raised doubts about the product's commercial viability.

In sum, because no facts are pled to show a motive to commit fraud or conscious recklessness, plaintiff's §10(b) claim should be dismissed.<sup>9</sup>

### **CONCLUSION**

For the reasons set forth above and in its moving brief, Flamel respectfully requests that all claims asserted against it should be dismissed with prejudice.

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<sup>9</sup> Because plaintiff has not properly alleged a §10(b) claim against Flamel or any of the individual defendants, her §20(a) claim must also fail. (Def. Br. at 18.) Further, plaintiff's request to amend her pleadings (Pltf. Br. at 16 n.8) should be denied because she has already amended her pleadings once; has not identified any new facts to support her claims; and, in all events, the text of the March 23, 2007 press release precludes, as a matter of law, any claim that she relied upon a material misleading statement in purchasing her Flamel stock.

Dated: August 19, 2008

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby declare that on August 19, 2008, I caused a true and correct copy of the foregoing to be electronically filed and to be served, by United States Mail, first-class postage prepaid on counsel for plaintiff at the following address:

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